

# AMERICAN COLLEGE of CARDIOLOGY



Heart House  
9111 Old Georgetown Road  
Bethesda, MD 20814-1699  
USA

301-897-5400  
800-253-4636  
Fax: 301-897-9745  
<http://www.acc.org>

April 11, 2000

Docket No. 00D-0053  
Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, (HFA-305)  
Rockville, MD 20852

**President**

George A. Beller, MD

**President-Elect**

Douglas P. Zipes, MD

**Immediate Past President**

Arthur Garson, Jr., MD, MPH

**Vice President**

W. Bruce Fye, MD, MA

**Secretary**

James T. Dove, MD

**Treasurer**

Michael J. Wolk, MD

**Chair, Board of Governors**

James T. Dove, MD

**Trustees**

Joseph S. Alpert, MD

Morton F. Arnsdorf, MD

George A. Beller, MD

Robert O. Bonow, MD

Robert M. Califf, MD

Melvin D. Cheitlin, MD

Michael H. Crawford, MD

Pamela S. Douglas, MD

James T. Dove, MD

Bernard W. D. Fong, MD

W. Bruce Fye, MD, MA

Arthur Garson, Jr., MD, MPH

Raymond J. Gibbons, MD

John W. Hirshfeld, Jr., MD

Sharon A. Hunt, MD

Spencer B. King, III, MD

Costas T. Lambrew, MD

Marian C. Limacher, MD

Bruce D. Lindsay, MD, ex officio

Ben D. McCallister, MD

Joseph V. Messer, MD

Steven E. Nissen, MD

Richard L. Popp, MD

Robert Roberts, MD

George W. Vetrovec, MD

L. Samuel Wann, MD, ex officio

W. Douglas Weaver, MD

William S. Weintraub, MD

Michael J. Wolk, MD

Douglas P. Zipes, MD

**Executive Vice President**

Christine W. McEntee

**RE: Docket No. 00D-0053; "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals"**

The American College of Cardiology (ACC) is pleased to offer its comments on the Food and Drug Administration's (FDA) two draft guidance documents, "Reprocessing and Reuse of Single-Use Devices: Review Prioritization Scheme" and "Enforcement Priorities for Single-Use Devices Reprocessed by Third Parties and Hospitals," as announced in the February 11, 2000 *Federal Register* (65 Fed Reg 7027).

The ACC is a 24,000-member non-profit professional medical society and teaching institution whose purpose is to foster optimal cardiovascular care and disease prevention through professional education, promotion of research, leadership in the development of standards and guidelines, and the formulation of health care policy. The College represents more than 90 percent of the cardiologists practicing in the United States.

The ACC supports the FDA's efforts to provide regulatory oversight to ensure that medical devices are reprocessed in such a way as to ensure their sterility and functionality. The ACC's interest in medical device reprocessing and reuse grows out of its concern for patient safety and the promotion of quality cardiovascular care. For more than 20 years, cardiovascular specialists have been safely using reprocessed electrophysiology (EP) catheters to treat their patients. EP catheters, used in the diagnosis and treatment of heart rhythm disorders, have been proven to be safe, effective, and cost efficient when properly reprocessed and reused.

The ACC endorses the comments of the North American Society of Pacing and Electrophysiology (NASPE), which are attached. Like NASPE, we urge the FDA to consider the body of peer-reviewed evidence available regarding the reuse of electrophysiology catheters in devising its final regulatory guidance documents.

00D-0053

C20

4931 '00 APR 11 A1 59

AMERICAN  
COLLEGE of  
CARDIOLOGY



9111 Old Georgetown Road  
Bethesda, MD 20814-1699 USA

301-443-8818

Messenger

Docket No. 00D-0053  
Dockets Management Branch  
Division of Management Systems and Policy  
Office of Human Resources and Management Services  
Food and Drug Administration  
5630 Fishers Lane  
Room 1061, (HFA-305)  
Rockville, MD 20852